

Attorney Docket No. 6197.214-US
Kanstrup et al.
Serial No. 10/621,302 Filed July 17, 2003
Via Facsimile No.: 1 571-273-8300

RESPONSE

This paper is sent in response to the non-final Office Action on the merits mailed April 27, 2005, which was supplemented by the non-final Office Action on the merits mailed June 22, 2005, which stated the response date was to be calculated from the mailing date of the June 22, 2005, document.

The examiner states in the Office Action Summary that claims numbered 1-10 are pending in the application; claims numbered 1-10 are rejected.

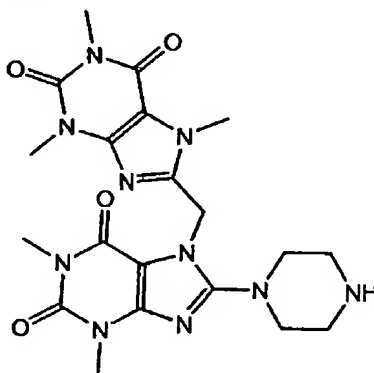
Applicant thanks the examiner for the telephonic interview conducted with the undersigned on November 18, 2005.

35 U.S.C. §112, Second Paragraph Rejection

The examiner has rejected claims numbered 1-10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the examiner states that:

(1) The fifth species excluded from claim 1 does not appear to belong in the first place. First, it appears to correspond to R1 = bond, because of the "methanediyl" part. A dimer would require a second carbon, one for the carbon to which R9 is attached, and a second for R1.

Applicant submits the structure for 1,3,1',3',7'-pentamethyl-8-piperazin-1-yl-3,7,3',7'-tetrahydro-7,8'-methanediyl-bis-purine-2,6-dione is as follows:



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which indicates R1 is *not* a bond as the examiner suggests. With respect to formula I, R9 and R10 are H, R1 is an optionally substituted heteroarylene. Applicant respectfully submits the exclusion of this compound is proper.

(2) Withdrawn by the examiner on November 18, 2005, as an inadvertent error on his part.

(3) Withdrawn by the examiner on November 18, 2005, as an inadvertent error on his part.

(4) The examiner states all choices for R1 must be written as divalent.

Applicant has amended claim 1 to comply with the examiner's request. Applicant notes neither the scope nor the interpretation of the claim has been changed by the amendments made to R1 regarding writing all choices as divalent.

(5) The examiner further states the "heteroaryl C1-C3 alkyl" choice for R1 is unclear: (a) is the heteroaryl a substituent on an alkylene, or (b) is the heteroaryl a part of the chain itself?

Applicant submits heteroaryl C1-C3 alkyl, when taken in context with the currently amended choices listed under R1 in claim 1, would be clear to a person skilled in the relevant art as the heteroaryl being part of the chain itself.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims numbered 1-10 under 35 U.S.C. §112, second paragraph.

35 U.S.C. §112, First Paragraph Rejection

The examiner has rejected claims numbered 3-10 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for other choices, does not reasonably provide enablement for 7-optionally substituted benzyl species.

The examiner stated in a telephonic interview conducted with the undersigned on November 18, 2005, that his rejection of the 7-optionally substituted benzyl species was an inadvertent error on his part.

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Applicant respectfully requests reconsideration and withdrawal of the rejection of claims numbered 3-10 under 35 U.S.C. §112, first paragraph.

35 U.S.C. §103(a) Rejection

The examiner has rejected claims numbered 1 and 2 under 35 U.S.C. §103(a) as being unpatentable over the single reference Romanenko, Farm. Zh. (Kiev) (5) 41-4, 1986, because 7-nonyl species would be an obvious variant of the 7-heptyl and 7-(3-chloro-but-2-enyl) species excluded by proviso from the present claims. The examiner notes the cited art species are taught as diuretics. Additionally, the examiner states two additional species, having 8-morpholino and 8-piperidino rings, rather than Applicant's 8-piperazino ring, renders the present claims obvious.

Applicant respectfully traverses the examiner's rejection. To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some suggestion or teaching of the desirability of making the specific combination that was made by the Applicant. See *In re Dance*, 160 F.3d 1339 (Fed. Cir. 1998). Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. See *B.F. Goodrich Co. V. Aircraft Breaking Sys. Corp.*, 72 F.3d 1577 (Fed. Cir. 1996). Further, a rejection cannot be predicated on the mere identification in the reference of individual components of the claimed invention. Particular findings must be made as to the reasons the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. See *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000). Applicant respectfully submits without reading into the art what Applicant teaches, the skilled artisan would not have been motivated to make the substitutions the examiner has suggested. That the construction in a particular art reference would have resulted in the claimed combination had it followed the "common practice" of attaching certain parts does not show obviousness at time of invention but rather reflects improper hindsight analysis and the reading into the art of the Applicant's own teachings. See *In re Deminski*, 796 F.3d 436 (Fed. Cir. 1986). Applicant respectfully asserts that generalizations should be avoided insofar as specific chemical structures are alleged to be *prima facie* obvious one from the other. Such a case must be based on support in the prior art for the structural change necessary to get

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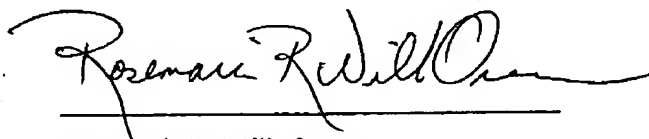
from the prior art compound to the claimed compound. See *In re Grabiak*, 769 F.2d, 226 (Fed. Cir, 1985).

Additionally, Applicant notes substantial differences in the utilities of the compounds of the present invention and those stated in the cited reference. The Board has held that substantial differences in utility are significant in the determination of obviousness. See *Ex parte Goonewardene*, 160 U.S.P.Q. 287 (Bd. Pat. App. 1968).

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims numbered 1-10 under 35 U.S.C. §103(a).

The examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



Date: November 18, 2005

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Use the following customer number for all correspondence regarding this application.

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